In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 19-632V
Filed: April 1, 2025

MARISSA SHEPPARD,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

John Leonard Shipley, Esq., Davis, CA, for petitioner.
Jamica Marie Littles, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On April 30, 2019, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10, *et seq.* (2012),[2] alleging that she suffered arthralgia, fatigue, and muscle weakness, diagnosed as mixed connective tissue disease ("MCTD") and polymyositis, caused by her influenza ("flu") vaccination that she received on September 19, 2017. (ECF No. 1.) For the reasons discussed below, I find that petitioner is *not* entitled to an award of compensation.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations,

[1] Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] All references to "§ 300aa" below refer to the relevant section of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury.

In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B). In many cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In that context, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines ex rel. Sevier v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991).

Neither MCTD nor polymyositis are injuries listed on the Vaccine Injury Table relative to any vaccine. 42 C.F.R. § 100.3(a). Accordingly, petitioner must satisfy the burden of proof for "causation-in-fact."

The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition and was a "but for" cause. *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" with the logical sequence being supported by "reputable medical or scientific explanation." *Althen*, 418 F.3d at 1278; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Ultimately, petitioner must satisfy what has come to be known as the *Althen* test, which requires: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. *Id*.

A petitioner may not receive a Vaccine Program award based solely on his or her assertions, but may support the petition with either medical records or by the opinion of a competent physician. § 300aa-13(a)(1). Medical records are generally viewed as particularly trustworthy evidence, because they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. § 300aa-13(b)(1). A petitioner may also rely upon circumstantial evidence. *Althen*, 418 F.3d at 1280. In that regard, the *Althen* court noted that a petitioner need not necessarily supply evidence from medical literature supporting petitioner's causation contention, so long as the petitioner supplies the medical opinion of an expert. *Id*. at 1279-80. While scientific certainty is not required, that expert's opinion must be based on "sound and reliable" medical or scientific explanation. *Boatmon v. Sec'y of Health & Human Servs*., 941 F.3d 1351, 1359 (Fed. Cir. 2019).

Cases in the Vaccine Program are assigned to special masters who are responsible for "conducting all proceedings, including taking such evidence as may be appropriate, making the requisite findings of fact and conclusions of law, preparing a decision, and determining the amount of compensation, if any, to be awarded." Vaccine Rule 3. Special masters must ensure each party has had a "full and fair opportunity" to develop the record but are empowered to determine the format for taking evidence based on the circumstances of each case. Vaccine Rule 3(b)(2); Vaccine Rule 8(a); Vaccine Rule 8(d). Special masters are not bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence in keeping with fundamental fairness to both parties. Vaccine Rule 8(b)(1). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." § 300aa-13(b)(1)(A). The special master is required to consider the entirety of record, draw plausible inferences, and articulate a rational basis for the decision. *Winkler v. Sec'y of Health & Human Servs.*, 88 F.4th 958, 963 (Fed. Cir. 2023) (citing *Hines*, 940 F.2d at 1528).

II. Procedural History

On April 30, 2019, petitioner filed her petition alleging that the flu vaccine she received on September 19, 2017, caused her to develop arthralgia, fatigue, and muscle weakness which was subsequently diagnosed as MCTD and polymyositis. (ECF No. 1.) Petitioner filed an affidavit and medical records marked as Exhibits 1-25 between April of 2019 and July of 2020. Respondent filed his Rule 4(c) Report in October of 2020 recommending against compensation. (ECF No. 30.) Respondent concluded that petitioner's alleged diagnosis of MCTD is unclear and unsupported, and also argued that petitioner's medical records lacked sufficient medical opinion to establish a medical

theory of causation for either causation-in-fact or significant aggravation. (*Id*. at 16.) Respondent further argued that onset of petitioner's condition is unclear. (*Id*. at 17.)

Following the filing of respondent's report, petitioner's initial counsel moved to withdraw from the case in March of 2021. (ECF No. 34.) Thereafter, no substantive progress was made in the case until petitioner's current counsel of record entered the case in May of 2022. (ECF No. 58.)

Petitioner filed an expert report by immunologist Marc Serota, M.D., along with supporting medical literature, in October of 2022. (ECF Nos. 65, 67-68; Exs. 30-39.) In February of 2023, respondent filed responsive reports and supporting medical literature from rheumatologist Chester Oddis, M.D., and immunologist Emanual Maverakis, M.D. (ECF Nos. 69-70; Exs. A-D.) Petitioner filed a supplemental report by Dr. Serota responding to respondent's experts along with updated rheumatology records and a letter from petitioner's treating rheumatologist. (ECF Nos. 74, 76; Exs. 40-43.)

The parties agreed to resolve this case on the written record without a hearing. (ECF No. 71.) Petitioner filed a motion for a ruling on the written record on September 14, 2023. (ECF No. 77.) Respondent filed his response on November 21, 2023. (ECF No. 79.) Petitioner filed her reply on December 15, 2023. (ECF No. 80.)

I have concluded that the parties have had a full and fair opportunity to develop the record and that it is appropriate to resolve this case without an entitlement hearing. S*ee Kreizenbeck v. Sec'y of Health & Human Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (citing *Simanski v. Sec'y of Health & Human Servs*., 671 F.3d 1368, 1385 (Fed. Cir. 2012)); *see also* Vaccine Rule 8(d); Vaccine Rule 3(b)(2).

III. Factual Summary

a. Pre-vaccination

On February 24, 2011, petitioner received both flu and Tdap vaccinations. (Ex. 20, p. 240.) About two weeks later, she presented to her primary care doctor with complaints of "more than a week" of diffuse myalgias, joint pain, and clavicular pain accompanied by fatigue. (*Id*. at 259-60.) In documenting the medical history, petitioner's primary care provider recorded that petitioner had received her flu and Tdap vaccinations three days prior to the onset of her symptoms but that petitioner had received prior vaccinations without any symptoms. (*Id.* at 259.) Physical exam revealed cervical adenopathy and she was diagnosed with lymphadenitis. (*Id*. at 260-61.) At a follow up encounter, it was noted that she was feeling slightly better after receiving antibiotics. (*Id.* at 269.) Her joint pains had mostly resolved; however, she still had swelling on her left side, below the clavicle and extending to the left side of the neck. (*Id.*) On exam, it was noted that her cervical adenopathy was not yet fully resolved. (*Id*. at 270-71.) Her physician noted that the cause of petitioner's condition was unclear given that there were no other signs of infection. (*Id.* at 271.) She considered whether it could be reactive changes following petitioner's vaccinations, but

concluded this was unlikely due to the duration of the symptoms. (*Id*.) Petitioner was started on prednisone through April 8. (*Id*. at 272)

Petitioner underwent a CT scan on March 18, 2011. (Ex. 20, p. 275.) While the scan did not show any mass around the clavicle, it did reveal mild pericardial fluid and mild infiltrate of soft tissue felt to be thymic hyperplasia[3] (*Id.* at 276), which raised a suspicion of myasthenia gravis given petitioner's fatigue. (*Id*. at 293.) However, petitioner's presentation was not consistent with that diagnosis and the etiology of left neck, shoulder, and chest pain was still felt to be of unclear etiology. (*Id*.) Although the fact of petitioner's preceding vaccinations was repeatedly mentioned, there is no medical opinion within the medical records implicating the vaccinations as a cause of her condition.[4]

On April 27, 2011, petitioner presented for care with a one-week history of right shoulder pain with finger numbness and a two-week history of right hip pain. (Ex. 20, p. 384.) On exam, petitioner had impingement and reduced range of motion of her shoulder, but her hip showed only tenderness with normal strength and range of motion. (*Id*. at 385.) Nothing in this encounter record associates these problems with petitioner's prior complaints of muscle and joint pain. (*Id*.) (Petitioner had other unrelated encounters in the interim. (*Id*. at 307-83.)) Only Ibuprofen was recommended for treatment. (*Id.* at 385.)

On June 3, 2011, petitioner returned to her primary care provider for follow up care regarding her right shoulder and hip pain. (Ex. 20, p. 427.) This time, in presenting her history, petitioner juxtaposed her right hip and shoulder pain beginning in April with her prior episode of diffuse joint pain occurring in March. (*Id.*) She also noted a prior issue with hip pain from 2005. (*Id*.) Review of systems indicated malaise, neck pain, and myalgia and joint pain. (*Id*. at 428.) Physical exam again showed reduced range of motion for the right shoulder and tenderness of the right hip. (*Id*.) Given petitioner's prior hip pain from 2005, it was suspected that petitioner merely had a recurrence of pain due to her job as an occupational therapist. (*Id.* at 429.) However, in light of the recent bout of diffuse joint pain and myalgia, the plan was to consult rheumatology. (*Id*.) Petitioner was diagnosed with bursitis of the hip, right shoulder pain, and arthralgia. (*Id.*) Lab work was also ordered. (*Id.* at 429-32.) Erythrocyte sedimentation rate ("ESR"), Rheumatoid factor ("RF"), antinuclear antibodies ("ANA"), and thyroid stimulating hormone ("TSH") were all within normal limits. (*Id*. at 429-31.)

[3] Hyperplasia is the "abnormal multiplication or increase in the number of normal cells in normal arrangement of tissue." *Hyperplasia*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=23964 (last visited Mar. 24, 2025).

[4] In her later rheumatology referral of June 2, 2011, petitioner's primary care physician indicated that petitioner was experiencing "recurrent" joint pain that started in January. (Ex. 20, p. 456.) This would, of course, place the onset of joint pain prior to the February 2011 vaccinations, though in the same referral she also refenced the symptoms as being "coincidental" to vaccination. (*Id*.)

Petitioner tested positive for Coccidioides immitis[5] IgM, but not IgG; however, it was noted that greater than 50% of positive results are not confirmed and it was sent to another lab for confirmation. (*Id*. at 431.) Petitioner's Creatine Kinase ("CK") came back elevated with her levels measuring at 208 IU/L. (*Id*. at 432.)

Petitioner was again placed on prednisone. (Ex. 20, p. 429.) However, about a week later, she reported to the emergency department for an adverse reaction to her third dose, which presented as chest pain, dizziness, headache, and high blood pressure. (*Id*. at 450.) She reported that her hip and shoulder pain were 85% better after just the first three doses of prednisone. (*Id*.) Petitioner's exam was normal, and she was instructed to proceed with her rheumatology evaluation. (*Id.* at 451.)

Petitioner was seen by rheumatology on June 14, 2011. (Ex. 20, p. 456.) She was diagnosed with arthralgia of multiple joints, bursitis of the shoulder, trochanteric bursitis, and a positive Coccidioides test. (*Id*. at 460.) A repeat of the Coccidioides test was ordered. (*Id*.) The rheumatologist noted that all testing for rheumatic conditions was negative and there are no signs of chronic arthritis. (*Id.* at 463.) Given that the joint pains flared at the same time petitioner had fluid around her heart sac, it was suspected that petitioner's bursitis was secondary to a viral infection. (*Id.*) It was noted petitioner may have a tendency for tendonitis, but there was no evidence of a chronic condition warranting anti-inflammatory therapy. (*Id*.) Petitioner was subsequently informed by e-mail that her initial positive result for Coccidioides had been confirmed negative. (*Id*. at 467.)

Beginning in February of 2012, petitioner sought care for right shoulder pain radiating down her arm. (Ex. 20, p. 708.) Her primary care provider diagnosed petitioner with rotator cuff syndrome and referred her to orthopedics for further evaluation. (*Id.* at 710.) Petitioner underwent an x-ray of her right shoulder which revealed loose body in the shoulder joint with calcific bursitis/tendonitis. (*Id.* at 721.) In March of 2012, an orthopedist diagnosed petitioner with calcific tendonitis with bursitis and cervical pain, noting a possible cervical radicular component. (*Id.* at 752-53.) Petitioner was also evaluated by physical medicine and rehabilitation in March of 2012. (*Id.* at 760.) The physical medicine physician assessed that petitioner had "cervical spine pain with scapular signs right" and diagnosed her with cervical radiculitis. (*Id.* at 764, 766.) Later that month, she reported low back pain radiating down her back leg, which was diagnosed as lumbar radiculopathy. (*Id.* at 814-15.) Petitioner returned to the orthopedist in April for her right shoulder pain and was diagnosed with right shoulder tendinitis and impingement. (*Id*. at 857-58.) She then returned to the physical medicine and rehabilitation provider who again assessed cervical radiculopathy; however, a follow up EMG was normal with no evidence of cervical radiculopathy. (*Id.* at 915,

[5] Coccidioides immitis is a pathogenic genus of anamorphic fungi found in San Joaquin Valley, California, southern California, and Mexico. The organism grows in the soil as "spore-forming saprophytic molds and in tissue as large, round, thick-walled spherules containing endospores." Inhalation of these spores causes coccidioidomycosis. *Coccidioides immitis*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=65729 (last visited Mar. 24, 2025); *Coccidioides*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=10312 (last visited Mar. 24, 2025).

1006.) Thus, in August of 2012, the physical medicine and rehabilitation physician indicated no further consultation was needed. (*Id.* at 1106.) Petitioner continued to pursue orthopedic treatment for her right shoulder, ultimately undergoing a right arthroscopic shoulder repair and subacromial decompression in September of 2014. (Ex. 6, pp. 324, 328-32.)

Petitioner reraised the issue of her right hip pain in January of 2013. (Ex. 20, pp. 1222-25.) In May of 2014, she presented to her primary care physician with complaints of "chronic recurrent hand pain and episodic swelling" which had been "[g]oing on for years." (Ex. 6, p. 136.) A history of shoulder, neck, hip, and knee pain was separately noted. (*Id.*) It was noted that her mother had suffered similar symptoms. (*Id*.) Review of systems was positive for joint pain and physical exam showed mild swelling of the hands. (*Id*. at 137.) It was noted that petitioner's prior rheumatology evaluation had been negative, but given the passage of time, a second evaluation was felt to be appropriate. (*Id.*) Petitioner was started on a prednisone taper. (*Id*.) Petitioner reported improvement with the prednisone (*Id*. at 142), and there is no indication petitioner sought a rheumatology evaluation.

After relocating, petitioner established care with a new primary care physician in September of 2016. (Ex. 5, pp. 83-84.) There is no indication that she discussed the above history with her new primary care physician at her initial encounter. She requested a neurology referral in follow up to a reported head injury from 2014.[6] (*Id.* at 83.) Physical exam was normal. (*Id*. at 84.) She returned to her new primary care provider in November for a complete physical. (*Id.* at 73.) She reported pain in her left arm below the shoulder that interfered with her ability to lift. (*Id.*) This issue had been present since July and was associated with exertion (lifting and pulling) related to her move. (*Id*.) She also had some other unrelated complaints. (*Id*.) She was referred to an orthopedist for her left shoulder complaint. (*Id*. at 76.) Ultimately, petitioner underwent arthroscopic surgery of the left shoulder in April of 2017, which included subacromial decompression and distal clavicle resection. (Ex. 22, p. 19.)

Petitioner started seeing a chiropractor for lower back pain on September 6, 2017. (Ex. 23.) Thereafter, she continued to see the chiropractor regularly through the remainder of 2017 and 2018. (*Id.*) She received the flu vaccination at issue in this case on September 19, 2017. (Ex. 1.)

b. Post-vaccination

On September 29, 2017, ten days post-vaccination, petitioner presented to her primary care provider reporting a possible allergic reaction to her flu vaccination. (Ex. 5, p. 52.) Her chief complaint was leg swelling and she also noted feeling fluid on her face and skin. (*Id*.) Specifically: "Patient reports that she woke up this morning and felt her left leg, knee, arm, hand and face are swollen with fluid and felt tight. also reports fatigue x few days." (*Id*.) Petitioner attributed her symptoms to a flu shot she had

[6] Petitioner would later have treatment for vertigo that was ultimately attributed to this incident. (Ex. 13, pp. 7, 10; Ex. 18.)

received a week prior and noted it had been her first flu vaccination in "many" years. (*Id.*) She indicated that she had previously been diagnosed with fluid around the heart following a prior vaccination and was concerned she may have an allergy. (*Id.*) However, she denied swelling of the chest at this encounter. (*Id*.) Petitioner reported a family history of muscle swelling, which they thought might be myositis. (*Id.*) Physical exam was normal except for the observation that petitioner's left leg had slightly greater girth than her right, though it was unclear whether this was an acute finding. (*Id*. at 53-54.) Petitioner also indicated that she felt her left hand, arms, and face felt swollen, but the doctor did not agree there was any noticeable swelling on examination. (*Id.* at 54.) Although the exam was "benign," follow lab work and a venous doppler of the lower extremity were ordered. (*Id*.) CK was abnormal, measuring 246 U/L against a reference range of 29-143 U/L, and ANA was positive. (*Id*. at 57.) CRP and ESR were normal. (*Id*. at 57-58.) Based on these lab results, petitioner was referred to rheumatologist Jagindra Mangru, M.D., as of October 3, 2017.[7] (*Id*. at 51.)

Petitioner returned to her primary care provider on October 5, 2017. (Ex. 5, p. 47.) Her chief complaint was "piercing pain" around the left side of her chest, which she placed in the context of her recent reaction to her flu shot, from which she had "experienced fluids, especially a knot and fluids around immunization area." (*Id*.) As of that day, petitioner was feeling "fluid in shoulders, chest, abdomen, goes up the neck, fluid tend[s to] shoot up chest." (*Id.*) Petitioner suggested this represented the same kind of reaction she had in response to her prior vaccination, which she indicated had been diagnosed as pericarditis. (*Id*.) Petitioner's exam was unrevealing, but she did have an abnormal ECG. (*Id*. at 49-50.) She was diagnosed with a hypersensitivity reaction, started on prednisone, and referred to cardiology. (*Id*. at 49.) Two days later, petitioner presented to the emergency department for her chest pain. (Ex. 8, p. 63.) After evaluation she was discharged with a diagnosis of unspecified (benign) chest pain. (*Id*. at 66-67.) As part of her emergency department evaluation, petitioner had further bloodwork done. (*Id.* at 69-73.) She again had elevated CK (256 IU/L vs a reference range of 33-211 IU/L).[8] (*Id*. at 71.) Petitioner had the recommended cardiology evaluation on October 9, 2017. (Ex. 25, p. 12.) The exam was normal, and the assessment was chest pain. (*Id.* at 14.) The cardiologist agreed with the recommendation for a follow up with rheumatology. (*Id*.) Petitioner subsequently had a normal stress test on October 20, 2017. (*Id.* at 10-11.)

[7] In addition to elevated CK and positive ANA, the referral also uses the diagnostic code for positive ribonucleoprotein ("RNP") antibody. (Ex. 5, p. 51); however, it does not appear that any RNP antibody test was included in petitioner's September 29, 2017 bloodwork. (*Id*. at 54-58.) After this was included in the referral, positive RNP is repeatedly listed in petitioner's "problem list/past medical" throughout her subsequent records from this provider. Petitioner later tested positive for RNP antibodies on November 2, 2017. (Ex. 4, p. 24.)

[8] Petitioner's subsequent cardiology evaluation indicates she also tested positive for ANA while in the emergency department (Ex. 25, p. 13); however, I could not locate any ANA test result in the emergency department records.

Petitioner returned to her primary care provider on October 12, 2017, to discuss her prednisone dosage. (Ex. 5, p. 44.) She was concerned about stopping the prednisone and reported that she had developed a ball under her left arm from her vaccination that resulted in left-side weakness and inability to move her arm. (*Id.*) She additionally reported nausea, muscle twitching, and a swelling sensation affecting the left side of her body, including her left leg. (*Id.*) She reported that her left leg felt "heavy" and that she feels "like her body is full of fluid" and she was also experiencing brain fog. (*Id*.) Physical exam was normal. (*Id.* at 45.) It was noted that petitioner's rheumatology evaluation was scheduled for November 3, 2017, and it was recommended that petitioner wait to see how she felt after discontinuing the steroids. (*Id*. at 44, 46.)

Petitioner presented to Dr. Mangru for the first time on November 2, 2017. (Ex. 4, p. 7.) She reported a history of "progressive myalgia, fatigue associated with weakness for several months duration." (*Id.*) It was noted she had tested positive for ANA and had elevated CK. (*Id.*) It was also noted that she had found prednisone to be "very helpful." (*Id*.) Petitioner was noted to have joint stiffness and systemic complaints of fatigue, muscle aches and weakness, and a generalized decrease in strength, but no other prior serious illnesses were noted. (*Id*.) Physical exam was normal and, in particular, the lack of Raynaud's phenomenon was recorded. (*Id*. at 8-9.) Petitioner was assessed as having myalgia, fatigue, and a raised antibody titer, with an inflammatory myopathy such as polymyositis being in the differential diagnosis pending additional lab results. (*Id*. at 9-10.) Lab work ordered that day was negative for ANA, but positive for ribonucleoprotein ("RNP") antibodies (2.2AI (reference range 0.0-0.9AI). (*Id*. at 24-25.) CK was 240 U/L (reference range 24-173 U/L). (*Id*. at 27.) Petitioner returned to Dr. Mangru on November 16, 2017, at which point she was assessed as having MCTD based on "polyarthralgia, myalgia associated with weakness and elevated CPK, abnormal ANA, and RNP antibody.[9] (Ex. 4, p. 11.) Petitioner was started on hydroxychloroquine sulfate and directed to use prednisone intermittently during symptom flares. (*Id*. at 13.)

Petitioner apparently developed a concern that her medications may be worsening her autoimmune condition. (Ex. 5, pp. 38-43.) As of January 30, 2018, she reported to Dr. Mangru that she discontinued hydroxychloroquine after only one month in favor of managing her condition naturally with diet changes. (Ex. 4, p. 15.) Petitioner reported feeling "relatively well at this time." (*Id*.) Petitioner was urged to resume treatment if symptoms returned. (*Id*. at 17.) Petitioner had bloodwork completed in connection with this encounter, which showed no abnormality. (*Id*. at 28-30.) In particular, ANA was negative. (*Id*. at 30.) Neither CK nor RNP were tested. The next day, petitioner presented to a naturopath, characterizing her condition as a vaccine reaction. (Ex. 3, p. 2.) As of a follow up with her primary care provider on February 19, 2018, petitioner characterized her condition as lupus, and lupus was then added to her

[9] In fact, the record states that petitioner was "recently diagnosed" with MCTD; however, MCTD is not specifically referenced in Dr. Mangru's November 2, 2017 record. (See Ex. 4, p. 7-10.)

assessment, though this had not been a part of Dr. Mangru's assessment. (Ex. 5, pp. 32-34.)

Thereafter, petitioner continued to seek care for her condition (as well as other complaints), but her assessment did not change. In June of 2018, she presented to urgent care with a complaint of left chest pain and leg swelling. (Ex. 7, p. 1.) The exam was unremarkable. (*Id.* at 2-3; Ex. 8, pp. 8-17.) As of July 24, 2018, petitioner restarted hydroxychloroquine. (Ex. 4, pp. 2-5.) Bloodwork from that encounter, including ANA, was negative. (*Id*. at 19-23.) Petitioner continued to manage her condition with Dr. Mangru's office, with records available through late 2022. (Exs. 9, 40.)

IV. Medical Opinions

a. For petitioner

i. Jagindra Mangru, M.D.[10]

Dr. Mangru prepared a letter dated August 2, 2023, for presentation in this case. (Ex. 41.) He indicates that:

> [Petitioner] has a chronic rheumatologic illness most consistent with a mixed connective tissue disease (MCTD) manifesting with polyarthralgia, fatigue, generalized muscle weakness, modest elevations in creatine kinase without myositis specific autoantibodies, abnormal antinuclear antibody (ANA) and ribonucleoprotein (RNP) antibody. Her diagnosis was initially established in November 2017.

(*Id*. at 1.)

Dr. Mangru notes that the American College of Rheumatology has no established criteria for MCTD and therefore relies on a 2019 set of consensus criteria originating in Japan. (Ex. 41, p. 1 (citing Yoshiya Tanaka et al., *2019 Diagnostic Criteria for Mixed Connective Tissue Disease (MCTD): From the Japanese Research Committee of the Ministry of Health, Labor, and Welfare for Systemic Autoimmune Diseases*, 31 MODERN RHEUMATOLOGY 29 (2021) (Ex. 44)).) Dr. Mangru cautions that these criteria are not definitive but indicates that petitioner does meet the criteria based on her polyarthritis,

[10] Dr. Mangru earned his medical degree from the University of the West Indies in Jamaica. (Ex. 42, p. 1.) He completed an internship at Princess Margaret Hospital in Nassau, Bahamas. (*Id.*) In 2002, Dr. Mangru completed his residency in internal medicine at Howard University Hospital in Washington, D.C. (*Id.*) He went on to complete a fellowship in rheumatology at the University of Iowa Hospitals and Clinics in 2004. (*Id.*) He is board certified in rheumatology and internal medicine and maintains his medical license in Georgia. (*Id.*) Dr. Mangru is a member of the American College of Rheumatology, among other organizations, and served as the President of the Georgia Society of Rheumatology from 2021 to 2022. (Ex. 41, p. 1.) Currently, he is the medical director of Cumming Rheumatology and Arthritis LLC. (Ex. 42, p. 2.) He is also has admitting privileges at Northside Forsyth Hospital in Cumming, Georgia. (Ex. 41, p. 1.) Dr. Mangru has been petitioner's treating rheumatologist since 2017. (*Id.*)

muscle weakness, elevated muscle enzymes, and her abnormal ANA with RNP antibody. (*Id*.) Given petitioner's initial inflammatory features and response to anti-inflammatory and immunomodulatory therapies, the MCTD diagnosis is "of a high clinical suspicion." (*Id.*) In particular, Dr. Magru notes that petitioner initially had a creatinine kinase level of 240, which improved to 148 with immunomodulatory treatment with accompanying symptom improvement, only to see symptoms worsen and creatine kinase to increase back to 249 with discontinuance of treatment. (*Id*. at 2.) Resumption of treatment brought petitioner's creatine kinase back down again to 180. (*Id*.)

In conclusion, Dr. Mangru indicates that "[i]n autoimmune conditions, testing must be interpreted in context of the clinical findings, and it is reasonable to utilize the clinical information including the chronicity of her symptoms, supportive laboratory data and response to treatment to aid in establishing a diagnosis." (Ex. 41, p. 2.) Thus, he opines "there is a reasonable clinical probability" that petitioner's MCTD diagnosis is accurate. (*Id*.)

Neither Dr. Mangru's letter nor his medical records include any opinion as to the cause of petitioner's MCTD. Dr. Mangru's treatment records indicate only that petitioner herself reported the flu vaccine as an allergy. (Ex. 40, pp. 52, 61, 70.)

ii. Marc Serota, M.D.[11]

Citing a review article by Nagy et al., Dr. Serota explains autoimmune diseases as "multietiological entities" involving genetic and environmental factors. (Ex. 30, p. 4 (citing György Nagy et al., *Selected Aspects in the Pathogenesis of Autoimmune Diseases*, 2015 MEDIATORS INFLAMMATION 351732 (2015) (Ex. 31)).) Whereas autoimmune processes occur in healthy individuals, kept in check by "various tolerance mechanisms," autoimmune diseases occur when these tolerance mechanisms fail due to environmental factors. (*Id*.) Such failure can lead to the persistence of self-reactive B and T cells, resulting in organ damage. (*Id*.) In addition to tolerance mechanisms, other factors can contribute to the development of autoimmune disease, including imbalance of pro- and anti-inflammatory cytokines. (*Id*. at 5.) With respect to MCTD in particular, Dr. Serota indicates that this condition is associated with elevated RNP autoantigens as well as increased cytokine levels and "a wide spectrum of T cell abnormalities." (*Id*.) Thus, relying on Nagy et al., Dr. Serota asserts that in MCTD

[11] Dr. Serota earned his medical degree from the University of Missouri Kansas City School of Medicine in 2007. (Ex. 39, p. 1.) In 2010, Dr. Serota completed his pediatric residency at Cohen's Children's Hospital in New Hyde Park, New York. (*Id.*) He completed a fellowship in allergy and immunology in 2012 at Children's Mercy Hospital in Kansas City, Missouri. (*Id.*) Additionally, Dr. Serota completed a dermatology residency in 2015 at the University of Colorado Denver. (*Id.*) He is triple board certified in allergy/immunology, dermatology, and pediatrics. (*Id.* at 3.) Currently, Dr. Serota is a physician at Peak Dermatology where he provides general and medical dermatology services as well as allergy, asthma, and immunology care. (*Id.* at 1.) Additionally, he is an attending dermatology physician at the Veteran's Affairs Hospital in Denver as well as a supervising physician in dermatology at the University of Colorado. (*Id.* at 1-2.) Dr. Serota has authored or co-authored 10 peer-reviewed articles and abstracts and has presented at over 25 lectures and professional conferences. (*Id.* at 3-6.)

"antigens or antigen/adjuvant combinations can induce an autoantigenic state" and lead to autoimmune disease. (*Id*.)

Citing Cusick et al., he further indicates that "molecular mimicry" is the "prevailing" hypothesis as to how viral antigens can initiate tissue-specific autoimmune damage. (Ex. 30, p. 5 (citing Matthew F. Cusick et al., *Molecular Mimicry as a Mechanism of Autoimmune Disease*, 42 CLINICAL REV. ALLERGY IMMUNOLOGY 102 (2011) (Ex. 32)).) He stresses a table included within that paper (Table 1) that includes a list of human diseases for which molecular mimicry is "possible" based on known antigen mimics. (*Id.* at 6 (discussing Cusick et al*., supra*, at Ex. 32, pp. 3-4).) Dr. Serota appears to cite this Table merely for the proposition that molecular mimicry is a valid concept. MCTD is not listed as a relevant disease and RNP is not listed as among the human antigens mimicked in any of the listed diseases at all, let alone as being mimicked by flu antigen. (*See* Cusick et al., *supra*, at Ex. 32, pp. 3-4.) Dr. Serota urges Guillain-Barré Syndrome ("GBS"), which is a condition affecting the peripheral nervous system, as "instructive" because it shows how the flu vaccine can be implicated as a cause of autoimmunity presumed to result from molecular mimicry; however, he does not substantiate any more direct connect between GBS and MCTD, which affect different tissues. (Ex. 30, p. 6.) Indeed, he explains that "[d]epending on what target the immune system mistakenly begins to attack, the phenotype of the disease would manifest differently . . . ."[12] (*Id.*)

In his supplemental report, Dr. Serota confirms that the papers by Nagy et al. and Cusick et al. form the basis for his opinion as to "how an adverse reaction to a vaccination could lead to an autoimmune condition such as MCTD." (Ex. 43, pp. 1-2.) However, he clarifies that he is not categorizing MCTD as "autoinflammatory," commenting in response to respondent's expert that "I have categorized it as an autoimmune disorder and certainly recognize the distinction." (*Id*. at 2.) Although he acknowledges the relevant literature suggests that influenza more frequently induces autoinflammatory conditions, he opines that this does not mean it is not possible for it to result less frequently in autoimmune conditions. (*Id*.)

To link the flu vaccine to MCTD, Dr. Serota discusses a paper by Watad et al., reporting on an international registry of 500 subjects suspected of having a condition known as "ASIA," which stands for Autoimmune Syndrome Induced by Adjuvants. (Ex. 30, p. 6 (citing Abdulla Watad et al., *Autoimmune/Inflammatory Syndrome Induced by Adjuvants (ASIA) Demonstrates Distinct Autoimmune and Autoinflammatory Disease Associations According to the Adjuvant Subtype: Insights from an Analysis of 500 Cases*, 203 CLINICAL IMMUNOLOGY 1 (2019) (Ex. 37)).) Citing both Watad et al. and an

[12] Dr. Serota's report also includes a cursory assertion that, in addition to molecular mimicry, hypersensitivity reactions have been described as affecting skin, joints, vessels, and glomeruli, and leading to recruitment of inflammatory cells. (Ex. 30, p. 6.) However, he did not provide any citation for this assertion, did not explain how it relates to his broader opinion, and did not specifically tie this concept to MCTD. In response, Dr. Maverakis observes that MCTD is not a serum sickness-like condition, or a hypersensitivity reaction, and that petitioner had normal complement levels. Accordingly, he asserts this discussion is not relevant to this case. (Ex. C, p. 14.)

additional review paper by Jara et al., Dr. Serota opines that the influenza vaccine is a major cause of ASIA. (*Id.* at 6-7 (citing Watad et al., *supra*, at Ex. 37; Luis J. Jara et al., *Severe Manifestations of Autoimmune Syndrome Induced by Adjuvants (Shoenfeld's Syndrome*, 65 IMMUNOLOGIC RSCH. 8 (2017) (EX. 38)).) Dr. Serota further asserts that Watad et al. showed that the median time from vaccination to presentation of disease is one week, which is consistent with the 10-day latency he asserts in this case, and that the cohort of ASIA subjects had symptoms similar to petitioner's condition and autoantibody profiles similar to petitioner. (*Id*. at 6-8.) Based on this, Dr. Serota opines that "there is an association between the influenza vaccine and MCTD." (*Id*. at 8.) Dr. Serota acknowledges that "a complete understanding of pathophysiologic mechanisms is not possible or known," but opines that "[g]iven that polygenic autoinflammatory disorders were more often reported after exposure to influenza vaccination, this diagnosis and triggering mechanism are in keeping with this data." (*Id*.)

Dr. Serota confirms that he agrees with the diagnosis of MCTD as rendered by the treating physicians. (Ex. 30, p. 7.) Further, he finds significance in the fact that petitioner developed edema in her extremities and face, fatigue, and autoimmune markers including ANA, RNP, and CK. (*Id*. at 7-8.) Ultimately, he opines that:

> Given the available data it is likely that as a result of antigenic and adjuvant stimulation of the immune system, combined with genetic predisposition and a loss of usual tolerance controls, that an aberrant T-cell response to self-antigens is formed which in the case of MCTD results in elevated serum concentrations of both type 1 and type 2 cytokines including an increase specifically in IL-10 producing CD4+ and CD8+ T cells. These responses are then manifested by increased measurable clinical markers in this case, where [petitioner] was found to have elevated CPK, and positive ANA and RNP antibodies, finding[s] which are in keeping with the above literature and demonstrate an autoimmune response.

(*Id*. at 8.)

b. For respondent

i. Chester Oddis, M.D.[13]

According to Dr. Oddis, MCTD is characterized first and foremost by high titer of anti-RNP antibodies accompanied by clinical features of other autoimmune conditions such as systemic lupus, systemic sclerosis, rheumatoid arthritis, or myositis. (Ex. A, p. 6.) In particular, MCTD patients "should" manifest swollen hands, inflammatory arthritis, myositis, Raynaud phenomenon,[14] and acrosclerosis[15] or sclerodactyly[16]. (*Id.*) MCTD patients "almost always" have Raynaud phenomenon. (*Id.*) Early clinical indicators may include puffy fingers, fatigue, arthralgias, myalgias, and low-grade fever. (*Id*.) Patients also have a high titer positive ANA, often with a speckled pattern. (*Id*.)

In petitioner's case, Dr. Oddis opines that petitioner does not have any features of any autoimmune disease and did not have Raynaud's phenomenon, inflammatory

[13] Dr. Oddis received his medical degree from Pennsylvania State University College of Medicine in 1980. (Ex. B, p. 1.) In 1984, he completed his internal medicine internship and residency also at Pennsylvania State University College of Medicine in Hershey, PA. (*Id.*) Thereafter, Dr. Oddis completed his rheumatology fellowship in 1987 at the University of Pittsburgh School of Medicine. (*Id.*) Since completing his fellowship, Dr. Oddis has held various academic appointments at the University of Pittsburgh School of Medicine and the Veteran's Affairs Medical Center in Pittsburgh. (*Id.* at 1-2.) Currently, he is a professor of medicine in the Division of Rheumatology and Clinical Immunology at the University of Pittsburgh School of Medicine. (*Id.* at 2; Ex. A, p. 1.) Dr. Oddis also currently serves as the Director of the Myositis Center at the University of Pittsburgh. (Ex. B, p. 2.) He is board certified in rheumatology and internal medicine and maintains his medical license in Pennsylvania. (*Id.* at 3.) Dr. Oddis has authored or co-authored over 150 peer-reviewed publications and over 60 review articles or book chapters. (*Id.* at 4-30; Ex. A, p. 2.) The primary focus of his research and clinical care is the clinical, epidemiologic, serologic, and treatment aspects of myositis and autoimmune interstitial lung disease. (Ex. A, p. 1.) Dr. Oddis has diagnosed and managed many patients with MCTD. (*Id.* at 2.)

[14] Raynaud phenomenon is "intermittent bilateral ischemia of the fingers, toes, and sometimes ears and nose, with severe pallor and often paresthesias and pain, usually brought on by cold or emotional stimuli and relieved by heat; it is usually due to an underlying disease or anatomic abnormality. When it is idiopathic or primary it is called Raynaud disease." *Raynaud phenomenon*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=97633 (last visited Mar. 24, 2025).

[15] Acrosclerosis is a type of systemic disorder of the connective tissue characterized by fibrosis with hardening and thickening of the skin as well as abnormalities of both microvasculature and larger vessels, that impacts the hands and feet, especially the digits, as well as the face and neck, in combination with Raynaud phenomenon. *Acrosclerosis*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=734 (last visited Mar. 24, 2025); *Systemic Scleroderma*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=105101 (last visited Mar. 24, 2025).

[16] Sclerodactyly is localized and chronic hardening and thickening of the skin in the digits. *Sclerodactyly*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=45001 (last visited Mar. 24, 2025); *Scleroderma*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=45002 (last visited Mar. 24, 2025).

arthritis, or myositis.[17] (Ex. A, pp. 6-7.) Although petitioner had one positive test for ANA, three subsequent ANA tests were negative. (*Id*.) Dr. Oddis opines that "persistently" positive ANA may be indicative of autoimmune disease, but not "transiently" positive ANA. (*Id*. at 6-7.) Additionally, although petitioner had a "low titer positive" RNP, this result occurred in connection with a negative ANA result. (*Id.* at 6.) This suggests it was a false positive as "a patient will never have a positive RNP autoantibody when an ANA is negative." (*Id*.) Therefore, it is "unclear" why petitioner was diagnosed with MCTD. (*Id*. at 7.) (Of note, Dr. Oddis's report was filed prior to petitioner's submission of Dr. Mangru's letter.)

With regard to Dr. Serota's theory of causation, he asserts that it is irrelevant because petitioner does not have an autoimmune condition and, in addition to three negative ANA results, "she never had any other laboratory features of autoimmunity including never having any elevated inflammatory markers." (Ex. A, p. 7.) Moreover, contrary to there being any logical sequence of cause and effect, he asserts that petitioner's post-vaccination physical exam of September 29, 2017 was normal and with normal inflammatory markers. (*Id*. at 7-8.)

ii. Emanual Maverakis, M.D.[18]

Like Dr. Oddis, Dr. Maverakis calls into question petitioner's diagnosis of MCTD. (Ex. C, pp. 10-13.) He does not agree that petitioner's ANA or RNP test results are diagnostic and also disagrees that petitioner's clinical presentation meets either the 2019 diagnostic criteria cited by Dr. Manju or an earlier set of criteria by Alarcón-Segovia. (*Id*. (citing D. Alarcón-Segovia & M.H. Cardiel, *Comparison Between 3 Diagnostic Criteria for Mixed Connective Tissue Disease: Study of 593 Patients*, 16 J. RHEUMATOLOGY 328 (1989) (Ex. C, Tab 5)).) Dr. Maverakis also opines that Dr. Serota's theory of causation is "self-contradictory and consists of foundational errors in its explanation of the molecular pathophysiology of autoimmunity." (*Id.* at 13.)

[17] Dr. Oddis acknowledges petitioner had slightly elevated creatine kinase, but notes that myositis is characterized by "much greater" elevation of creatine kinase that is also accompanied by elevated aldolase, which petitioner did not have. (*Id*. at 6-7.)

[18] Dr. Maverakis completed a research fellowship in immunology and earned his medical degree at Harvard Medical School in 2000 and 2003 respectively. (Ex. D, p. 2.) From 2000 to 2002, he served as a Howard Hughes Fellow at Howard Hughes Medical Institute and the La Jolla Institute for Immunology where he studied molecular mimicry and epitope spreading as well as T cell antigen processing. (*Id.*; Ex. C, p. 1.) Thereafter, Dr. Maverakis completed his internship in internal medicine at Beth Israel Deaconess Medical Center in 2003 and his dermatology residency at the University California Davis in 2007. (Ex. D, p. 2.) Since completing his residency, Dr. Maverakis has held various academic appointments at the University of California Davis in Sacramento. (*Id.* at 2-3.) Currently, he serves as a tenured professor in the Departments of Dermatology and Medical Microbiology and Immunology at the University of California Davis. (*Id.* at 3.) He also serves as the Director of the Immune Monitoring Shared Resource and as the Associate Director of Metabolism and Immunologic Health at the University of California Davis Foods for Health Institute. (*Id.*) He is board certified in dermatology and clinical informatics and maintains his medical license in California. (*Id.* at 2; Ex. C, p. 1.) Dr. Maverakis is a Diplomate of the American Board of Dermatology. (Ex. D, p. 2.) He has published over 150 peer-reviewed journal articles and over 20 book chapters on various dermatological issues. (*Id.* at 6-23.)

Dr. Maverakis notes that the Nagy et al. paper does not primarily relate to MCTD in particular. (Ex. C, p. 14.) Although Nagy et al. references IL-10 producing T cells as important to the pathophysiology of MCTD, this proposed pathophysiology conflicts with other descriptions of the relevant autoimmune pathophysiology included in other papers cited by Dr. Serota. (*Id*.) Specifically, Cusick et al., on which Dr. Serota otherwise places significant emphasis regarding the etiology of autoimmunity, does not discuss IL-10 as among the cytokines implicated in the induction of autoimmunity. (*Id*.) In any event, the flu vaccine does not induce a robust CD8+ T cell response and does not increase IL-10. (*Id*. (citing P. Friedrich et al., *Comparing Humoral and Cellular Immune Response Against HBV Vaccine in Kidney Transplant Patients*, 15 AM. J. TRANSPLANTATION 3157 (2015) (Ex. C, Tab 10); Gounwa Awad et al., *Robust Hepatitis B Vaccine-Reactive T Cell Responses in Failed Humoral Immunity*, 21 MOLECULAR THERAPY: METHODS & CLINICAL DEV. 288 (2021) (Ex. C, Tab 11); Kawsar R. Talaat et al., *Rapid Changes in Serum Cytokines and Chemokines in Response to Inactivated Influenza Vaccination*, 12 INFLUENZA & OTHER RESPIRATORY VIRUSES 202 (2018) (Ex. C, Tab 12)).) According to Dr. Maverakis, Dr. Serota has not demonstrated that the flu vaccine induces meaningful production of any of the cytokines discussed by either Nagy et al. or Cusick et al. (*Id*.)

Dr. Maverakis also suggests that Dr. Serota's discussion of Watad et al. conflates autoimmune disease and autoinflammatory disease. (Ex. C, p. 15.) He asserts that the two types of conditions have distinct cytokine profiles and that Dr. Serota's reliance on IL-10-secreting T cells suggests that MCTD is an autoimmune disease rather than an autoinflammatory disease. (*Id*.) Watad et al. likewise characterize MCTD as an autoimmune condition. (*Id.*) Thus, to the extent Dr. Serota quotes Watad et al. as indicating that the flu vaccine is more often associated with autoinflammatory disorders, this undercuts the notion that MCTD can be caused by the flu vaccine. (*Id*.) Moreover, Dr. Maverakis doubts the Watad et al. findings (based on 500 subjects versus annual 150 million annual administration of the flu vaccine) represent genuine findings, and thus have a high likelihood of being chance findings erroneously linked to vaccination. (*Id*. at 16-17.)

V. Party Contentions and Issues to be Decided

Petitioner asserts that her diagnosis of MCTD is established by her treating rheumatologist, Dr. Mangru, who is well qualified to render this diagnosis. (ECF No. 77, p. 13.) She asserts that respondent's experts are focused too narrowly on limited laboratory data to the exclusion of her complete clinical picture. (*Id.; see also* ECF No. 80, pp. 2-3.) She further asserts that her expert, Dr. Serota, has presented a sound and reliable medical theory pursuant to *Althen* prong one establishing that, while a complete understanding of the pathophysiology of MCTD is not available, antigenic and adjuvant stimulation of the immune system, combined with genetic predisposition and loss of immune tolerance, can lead to an aberrant T-cell response to self-antigens resulting in MCTD. (*Id*. at 15.) Petitioner disclaims "ASIA" as a "primary" basis for Dr. Serota's opinion. (ECF No. 80, p. 7.) Petitioner stresses that she was found to have elevated CK and tested positive for ANA and RNP antibodies. (ECF No. 77, p. 15.) Regarding

Althen prong two, she also stresses the fact of her MCTD diagnosis, the timing of onset (which she asserts to be 10 days post-vaccination), the fact of a prior adverse reaction to the flu vaccine, and the lack of any alternative cause for her MCTD. (*Id*. at 16; *see also* ECF No. 80, pp. 4-5.) Regarding *Althen* prong three, petitioner asserts that Dr. Serota has established that a 10-day post-vaccination onset is consistent with the known timing for the development of autoimmunity following vaccination, which he asserts typically occurs "with days to weeks" of vaccination. (*Id*. at 17.) Petitioner acknowledges that she had similar symptoms in years prior but asserts that those symptoms likewise followed a flu vaccination and that she was symptom-free at the time of the vaccination in question. (ECF No. 80, p. 7.)

Respondent contests that petitioner has preponderantly established a diagnosis of MCTD, a point he asserts as a threshold issue. (ECF No. 79, pp. 16-19.) Respondent contends that petitioner did not actually test positive for RNP antibodies and asserts that petitioner's single positive test for ANA is not informative. (*Id.*) He also disputes that petitioner's clinical presentation is consistent with the clinical definition of MCTD. (*Id*. at 16.) He acknowledges Dr. Mangru's diagnosis but contends that petitioner overstates Dr. Mangru's involvement in her treatment and argues that the diagnosis was not reliably reached. (*Id*. at 17-19.) Addressing petitioner's claim of vaccine-caused MCTD *arguendo*, respondent contends that Dr. Serota's theory is "nothing more than a generalized description of molecular mimicry," lacking any specific nexus to MCTD. (*Id*. at 19-20.) Respondent further argues against Dr. Serota's invocation of the "ASIA" registry to support a pathologic role for adjuvants. (*Id.* at 21-22.) Even if the Court were to assume ASIA is a reliable theory, which he stresses it is not, respondent argues that it is more likely than not that the flu vaccine at issue was not adjuvanted. (*Id*. at 22-23.) Regarding *Althen* prong two, respondent contends there is no compelling evidence to support a logical sequence of cause-and-effect implicating petitioner's vaccination in the development of her injury. (*Id.* at 24-25.) Petitioner's *Althen* prong two showing is limited to an attempt to rely on a temporal relationship and lack of alternative explanation, which is inadequate. (*Id*.) Finally, respondent disputes that petitioner can meet her burden of proof under *Althen* prong three, both because her proposed theory should not be credited and because he contends the symptoms underlying her alleged MCTD diagnosis predate the vaccination at issue. (*Id*. at 26-28.)

Ordinarily, where the identity and nature of the vaccine-related injury is in dispute, the Federal Circuit has concluded that it is "appropriate for the special master to first determine what injury, if any, [is] supported by the evidence presented in the record before applying the *Althen* test to determine causation." *Lombardi v. Sec'y of Health & Human Servs.*, 656 F.3d 1343, 1352-53 (Fed. Cir. 2011). In this case, however, even assuming *arguendo* that petitioner suffered MCTD as alleged, petitioner cannot preponderantly demonstrate that her condition was vaccine-caused for the reasons discussed below. Thus, because an *Althen* analysis based on petitioner's alleged condition and preferred diagnosis is in any event dispositive, I assume, but do not decide, that petitioner suffered MCTD.[19] Ultimately, "the function of a special master

[19] This should not be construed as an indication that petitioner would be likely to prevail on the question of diagnosis. Although petitioner carries a diagnosis of MCTD from a treating rheumatology expert,

is not to 'diagnose' vaccine-related injuries." *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1382 (Fed. Cir. 2009). Instead, the special master must determine, "based on the record evidence as a whole and the totality of the case, whether it has been shown by a preponderance of the evidence that a vaccine caused the [petitioner's] injury." *Id.* (quoting *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 549 (Fed. Cir. 1994)).

VI. Discussion

a. *Althen* prong one

Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received can cause the type of injury alleged. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (citation omitted). Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen*, 35 F.3d at 548-49. Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *See Andreu*, 569 F.3d at 1378-79 (citing *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325-26 (Fed. Cir. 2006)). However, "[a] petitioner must provide a 'reputable medical or scientific explanation' for [their] theory." *Boatmon*, 941 F.3d at 1359 (quoting *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010)). "While it does not require medical or scientific certainty, it must still be 'sound and reliable.'" *Id.* (quoting *Knudsen*, 35 F.3d at 548-49).

Much of Dr. Serota's opinion is devoted to discussing broadly the immunology underlying MCTD autoimmunity without directly tying those concepts to the flu vaccine. However, even if accepted over Dr. Maverakis's criticisms, demonstrating that MCTD is an autoimmune condition is insufficient to meet petitioner's burden of proof under *Althen* prong one. While establishing a condition as autoimmune may be predicate to a viable theory of causation, it does not in itself implicate any vaccination as a cause or trigger of autoimmunity. *E.g. Fiorello v. Sec'y of Health & Human Servs*., No. 17-1869V, 2024 WL 4133302, at *14 (Fed. Cl. Spec. Mstr. Aug. 12, 2024) (explaining that "[t]here is no question that autoimmunity is an established category of disease that can, in at least some instances, be linked to vaccination. However, there are various pathways to autoimmunity and many autoimmune conditions have little to no suspicion of vaccine causation." (internal citation omitted)), *mot. rev. den'd* 2025 WL 748000 (Fed. Cl. Feb. 20, 2025); *Casazza v. Sec'y of Health & Human Servs*., No. 17-947V, 2023 WL 6214984, at *10 (Fed. Cl. Spec. Mstr. Aug. 30, 2023) (explaining that "there is no dispute that RA is an autoimmune condition of uncertain cause that generally involves a combination of genetic and environmental factors or stimuli . . . [but] [v]ery little on this record apart from Dr. Gershwin's say-so associates any vaccine with RA whereas much more purports to refute Dr. Gershwin's opinion.").

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respondent's experts have raised significant questions, which this decision leaves unresolved, as to whether that diagnosis can be supported.

Prior petitioners have been unsuccessful in seeking to provide theories of causation establishing that vaccines, including the flu vaccine, can cause or aggravate connective tissue disorders such as MCTD. *Volpe v. Sec'y of Health & Human Servs.*, No. 16-1422V, 2022 WL 16730561, at *19-26 (Fed. Cl. Spec. Mstr. Oct. 12, 2022) (finding petitioner failed under *Loving* prong four to demonstrate that the flu vaccine can significantly aggravate UCTD); *S.E.H. v. Sec'y of Health & Human Servs*., No. 15-260V, 2018 WL 6920509, at *71-73 (Fed. Cl. Spec. Mstr. Dec. 20, 2018) (finding that the petitioner failed to establish under *Althen* prong one that the flu vaccine can cause MCTD, noting petitioner's molecular mimicry presentation to be "too simplistic."); *see also Burgess v. Sec'y of Health & Human Servs.,* No. 17-688V, 2022 WL 17410582, at *29-31 (Fed. Cl. Spec. Mstr. Nov. 7, 2022) (finding the petitioner failed to demonstrate under *Loving* prong four that the Tdap vaccine can significantly aggravate UCTD)*; Roby v. Sec'y of Health & Human Servs*., No. 15-125V, 2020 WL 6240619, at *20-21 (Fed. Cl. Spec. Mstr. Sept. 10, 2020) (finding that the petitioner failed to establish under *Althen* prong one that the hepatitis B vaccine can cause MCTD through bystander activation, which was "speculative" as presented). Additionally, to the extent MCTD may overlap with other rheumatologic conditions such as rheumatoid arthritis, systemic lupus erythematous ("SLE"), or polymyositis (*see* Tanaka et al., *supra*, at Ex. 44, p. 1), prior petitioners have likewise failed to connect these conditions to vaccination as well. *E.g. Casazza*, 2023 WL 6214984, at *10-14 (finding the petitioner failed to establish that the flu vaccine can cause rheumatoid arthritis); *Chambers v. Sec'y of Health & Human Servs*., No. 19-140V, 2022 WL 3369332, at *21 (Fed. Cl. Spec. Mstr. July 22, 2022) (explaining that "[i]n the Program, SLE and other forms of lupus have not been addressed frequently as possible vaccine injuries. None of the reasoned decisions involving SLE, however, that I have been able to identify have resulted in the determination that the petitioner established causation."); *McDaniel v. Sec'y of Health & Human Servs*., No. 17-1322V, 2023 WL 4678688, at *29-32 (Fed. Cl. Spec. Mstr. June 26, 2023) (finding petitioner had not established that the flu vaccine can cause polymyositis).[20]

While molecular mimicry, as cited by Dr. Serota, "is a generally accepted scientific principle, mere invocation of the scientific term does not carry a petitioner's burden in a Program case." *Deshler v. Sec'y of Health & Human Servs*., No. 16-1070V, 2020 WL 4593162, at *20 (Fed. Cl. Spec. Mstr. July 1, 2020) (citing *Forrest v. Sec'y of Health & Human Servs.*, No. 14-1046V, 2019 WL 925495, at *3 (Fed. Cl. Spec. Mstr. Jan. 28, 2019)); *see also Caredio v. Sec'y of Health & Human Servs.*, No. 17-0079V, 2021 WL 4100294, at *31 (Fed. Cl. Spec. Mstr. July 30, 2021) (noting that "demonstration of homology alone is not enough to establish a preponderant causation theory" (emphasis omitted)), *mot. for rev. denied*, 2021 WL 6058835 (Fed. Cl. Dec. 3, 2021). Dr. Serota relies on Cusisk et al. for the proposition that molecular mimicry can be a viable explanation for flu vaccine caused autoimmunity leading to MCTD; however, that paper, despite identifying numerous "possible" antigen mimics, conspicuously does

[20] Of course, prior decision by special masters and the Court of Federal Claims are not binding and do not dictate the outcome of this case. *Boatmon*, 941 F.3d at 1358-59; *Hanlon v. Sec'y of Health & Human Servs*., 40 Fed Cl. 625, 630 (1998).

not list MCTD as among the resulting conditions and does not otherwise list RNP as among the human antigens mimicked in any of the listed diseases at all, let alone as being mimicked by flu antigen. (*See* Cusick et al., *supra*, at Ex. 32, pp. 3-4.)

Dr. Serota attempted to link the flu vaccine to autoimmunity broadly by reference to GBS (Ex. 30, p. 6); however, Dr. Serota has not established that the pathophysiology of GBS is sufficiently similar to MCTD such that a reasonable analogy could be drawn. Whereas there is epidemiologic data implicating certain flu vaccines as a cause of GBS, no such data exists relative to MCTD. Moreover, even setting aside a specific association to vaccination, GBS is otherwise generally understood as a post-infectious syndrome, which is not the case for MCTD. And, in any event, the two conditions (GBS and MCTD) involve different body systems. This is especially relevant given Dr. Serota's invocation of molecular mimicry. He acknowledged that different disease phenotypes result "[d]epending on what target the immune system mistakenly begins to attack." (*Id.*) Again, this speaks broadly to the general concept of autoimmunity without any support for the proposition that the ability of the flu vaccine to cause one type of autoimmune attack can evidence its ability to cause another type of autoimmune attack leading to an entirely different disease phenotype.

Importantly, a petitioner does not prevail merely by invoking a vaccine's intended immune response without evidence that it could be pathologic. *See Elvira ex rel. D.E. v. Sec'y of Health & Human Servs.*, No. 17-531V, 2024 WL 4966035, at *20 (Fed. Cl. Spec. Mstr. Nov. 6, 2024); *Vanore v. Sec'y of Health & Human Servs.*, No. 21-0870V, 2024 WL 3200287, at *18 (Fed. Cl. Spec. Mstr. May 31, 2024); *Kalajdzic v. Sec'y of Health & Human Servs.*, No. 17-792V, 2022 WL 2678877, at *23 (Fed. Cl. Spec. Mstr. June 17, 2022), *mot. for rev. den'd*, 2024 WL 4524777 (Fed. Cl. Oct. 18, 2024), *aff'd*, 2024 WL 3064398 (Fed. Cir. June 20, 2024); *Cordova v. Sec'y of Health & Human Servs.*, No. 17-1282V, 2021 WL 3285367, at *17 (Fed. Cl. Spec. Mstr. June 23, 2021). Here, in addition to the above, Dr. Maverakis observes that Dr. Serota's causal opinion suffers a disconnect in its attempt to link the immunology underlying MCTD to a post-vaccinal immune response.

Although Dr. Serota cites Cusick et al. for the proposition that proinflammatory cytokines can facilitate autoimmune disease generally, Dr. Maverakis explains that Dr. Serota's discussion of MCTD autoimmunity otherwise places particular emphasis on a pathophysiologic role for IL-10 producing CD8+ T cells, which is not discussed by Cusick et al. (Ex. C, p. 14 (discussing Cusick et al., *supra*, at Ex. 32).) Moreover, while Dr. Serota provided no direct evidence that the flu vaccine produces either the IL-10 discussed by Nagy et al. or the other proinflammatory cytokines discussed by Cusick et al., Dr. Maverakis cited literature specifically refuting that the flu vaccine produces significant CD8+ T cells or ultimately meaningfully increases production of IL-10. (Ex. C, p. 14 (citing Friedrich et al., *supra*, at Ex. C, Tab 10; Awad et al., *supra*, at Ex. C, Tab 11; Talaat et al., *supra*, at Ex. C, Tab 12).) In his responsive report, Dr. Serota did not challenge this point or discuss Dr. Maverakis's supporting literature.[21] (Ex. 43.)

[21] It does not appear from Dr. Serota's report that he is necessarily proposing that the flu vaccine *directly* results in elevation of IL-10 producing CD4+ CD8+ T cells. Rather, he suggests that an unspecified

Dr. Maverakis also contended that Dr. Serota's initial report conflated the pathophysiology of autoimmunity and autoinflammation. (Ex. C, p. 15.) He opined that the flu vaccine is more likely to be a cause of autoinflammation than autoimmunity. (*Id.*) In his second report, though maintaining that autoimmunity and autoinflammation exist on a "spectrum," Dr. Serota confirmed that he is not opining that MCTD is autoinflammatory and that he "certainly recognize[s] the distinction." (Ex. 43, p. 2.) And, although Dr. Serota stressed that "less frequently" cannot be equated with "never or not at all," he accepted Dr. Maverakis's premise that there is a greater likelihood that a flu vaccine would cause an autoinflammatory disorder, which is not at issue in this case. (*Id.*)

Ultimately, the only evidence on this record apart from Dr. Serota's *ipse dixit* purporting to implicate vaccination as a cause of MCTD is the literature he cited pertaining to the so-called ASIA hypothesis. (Ex. 30, pp. 6-7 (citing Watad et al., *supra*, at Ex. 37; Jara et al., *supra*, at Ex. 38).) There are several issues with Dr. Serota's reliance on this literature.

First, the ASIA hypothesis is not sound and reliable. *E.g.*, *J.F. v. Sec'y of Health & Human Servs.*, 13-799V, 2022 WL 5434214, at *29-32 (Fed. Cl. Spec. Mstr. Sept. 9, 2022) (finding petitioner unpersuasive in arguing that ASIA is a sound and reliable theory of causation under *Althen* prong one); *Decker v. Sec'y of Health & Human Servs.*, No. 15-017V, 2020 WL 7889059, at *32 (Fed. Cl. Spec. Mstr. Dec. 14, 2020) (noting that ASIA is a theory that has been unsuccessful and repeatedly rejected in the Vaccine Program); *D'Angiolini v. Sec'y of Health & Human Servs.*, 122 Fed. Cl. 86, 102 (2015) (holding that the special master did not err in "determining that ASIA does not provide[] a biologically plausible theory for recovery" in the Vaccine Program), *aff'd*, 645 F. App'x. 1002 (Mem.) (Fed. Cir. 2016); *Salerno v. Sec'y of Health & Human Servs.*, 16-1280V, 2020 WL 3444163, at *11 (Fed. Cl. Spec. Mstr. May 29, 2020) (finding ASIA to be an unreliable theory that has been uniformly rejected as unsupported and unreliable in prior cases); *Suliman v. Sec'y of Health & Human Servs.*, 13-993V, 2018 WL 6803697, at *27 (Fed. Cl. Spec. Mstr. Nov. 27, 2018) ("No special masters have ever found ASIA or ASIA-like theories to be persuasive."). A prior petitioner likewise sought unsuccessfully to invoke epidemiology exploring the ASIA hypothesis in the same context as this case, namely seeking to find support for the idea that the flu vaccine can be causally implicated in the development of connective tissue disorders and citing to

aberrant T-cell response would initiate the process to result in such elevations as a downstream consequence. (Ex. 30, p. 8.) However, even accepting that this could be responsive to Dr. Maveraskis's criticism that the flu vaccine has not been shown to produce IL-10 producing CD8+ T cells, this simply has the effect of highlighting that Dr. Serota's opinion hinges on an initial, unspecified "aberrant T-cell response" that is utterly vague and unsupported. To the extent Dr. Serota bases this aspect of his opinion on Nagy et al., that paper does not provide any greater detail. The authors' conclusions are tentative and broadly stated. They indicate that "MCTD is characterized by a wide spectrum of T-cell abnormalities" and, contrary to Dr. Serota, appear to suggest that IL-10 producing T cells may be compensatory rather than causal. (Nagy et al., *supra*, at Ex. 31, p. 4.) Of course, Dr. Maverakis also ultimately disputes that the findings underlying Nagy et al.'s discussion are actually significant findings. (Ex. C, p. 14.) But in any event, only Dr. Serota's *ipse dixit* suggests that the flu vaccine can produce an aberrant T cell response within the spectrum of abnormalities discussed by Nagy et al.

Watad et al. paper, in particular. *Volpe*, 2022 WL 16730561, at *11. In that case, as I conclude in this case, respondent's expert was found persuasive in contending that the ASIA concept is flawed and that it does not provide evidence of pathogenesis. *Id.* at *17, 25.

Additionally, even accepting petitioner's representation that ASIA is not a primary component of petitioner's theory (ECF No. 80, p. 7), the Watad et al. paper on which Dr. Serota nonetheless relies is in itself not reliable. In fact, I have previously addressed the merits of the Watad et al. paper in a prior case that sought to rely on "ASIA" as a theory of causation. *See J.F.*, 2022 WL 5434214, at *32. The paper is not reliable because the ASIA registry "is circular – bringing subjects into the registry because they have ASIA and then using the fact that they meet the diagnostic criteria to validate the criteria." *Id*. While the authors purport to be using the registry to refine subtypes of adjuvant responses, the entire exercise incorporates a selection bias. *Id*. Lastly, even taking the paper entirely at face value, it purports to find only the hepatitis B vaccine as a statistically significant cause of well-defined autoimmune diseases. (Watad et al., *supra*, at Ex. 37, pp. 2-3.) To the extent one could argue individuals within the ASIA registry could nonetheless be utilized as case reports, this would not be strong evidence. *Crutchfield v. Sec'y of Health & Human Servs.*, No. 09-0039V, 2014 WL 1665227, at *19 (Fed. Cl. Spec. Mstr. Apr. 7, 2014) ("[S]ingle case reports of Disease X occurring after Factor Y . . . do not offer strong evidence that the *temporal* relationship is a *causal* one—the temporal relationship could be pure random chance."), ***aff'd***, 125 Fed. Cl. 251 (2014); *but see Paluck v. Sec'y of Health & Human Servs.*, 104 Fed. Cl. 457, 475 (2012) (explaining that case reports are not entirely devoid of evidentiary value).

In light of the above, and considering the record as a whole, petitioner has not established by preponderant evidence that there is a sound and reliable theory of causation available to establish that the flu vaccine can cause MCTD.

b. *Althen* prong two

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326-27; *Grant*, 956 F.2d at 1147-48. Medical records are generally viewed as particularly trustworthy evidence. *Cucuras*, 993 F.2d at 1528. However, medical records and/or statements of a treating physician's views do not *per se* bind the special master. *See* § 300aa-13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 745 n.67 (2009) ("[T]here is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted."). A petitioner may support a cause-in-fact claim through either medical records or expert medical opinion. § 300aa-13(a). The special master is required to consider all the relevant evidence of record, draw

plausible inferences, and articulate a rational basis for the decision. *Winkler*, 88 F.4th at 963 (citing *Hines*, 940 F.2d at 1528).

Regarding *Althen* prong two, petitioner stresses the fact of her MCTD diagnosis, the timing of onset (which she asserts to be 10 days post-vaccination), the fact of a prior adverse reaction to the flu vaccine, and the lack of any alternative cause for her MCTD. (ECF No. 77, p. 16; *see also* ECF No. 80, pp. 4-5.) However, none of these points are ultimately persuasive.

"[T]reating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Capizanno* 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1280). Here, however, while petitioner repeatedly reported the flu vaccine as an allergy (Ex. 40, pp. 52, 61, 70), Dr. Mangru never opined that petitioner's condition was caused by her vaccination. Even after being specifically prompted to write a letter on petitioner's behalf to support her vaccine injury claim, Dr. Mangru stopped short of offering any assessment as to the underlying cause of petitioner's condition. (Ex. 41.) Even if one assumes that petitioner's condition began 10 days post-vaccination, the Federal Circuit has explained that "[a]lthough probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." *Althen*, 418 F.3d at 1278 (citing *Grant*, 956 F.2d at 1149).

Petitioner stresses that she was found to have elevated CK and tested positive for ANA and RNP antibodies. (ECF No. 77, p. 15.) Additionally, Dr. Mangru noted that petitioner's condition had "inflammatory features," referring to polyarthralgia, muscle weakness, fatigue, and stiffness. (Ex. 41, p. 2.) However, if credited, these observations are merely diagnostic of the MCTD itself. Yet, for all the reasons discussed under *Althen* prong one, there is little to no reason to suspect that MCTD can be vaccine caused and the fact that MCTD is an autoimmune condition is not informative in itself. Nor are petitioner and Dr. Serota persuasive in seeking to rely on the presence of a prior vaccine reaction as some evidence supporting a logical sequence of cause and effect. Only petitioner's subjective belief links her condition in 2011 and her condition in 2017.

As Dr. Oddis observed, petitioner's bloodwork from September 29, 2017 did not show any elevation in inflammatory markers. (Ex. A, pp. 7-8 (discussing Ex. 5, pp. 54-58).) And, although Dr. Mangru's letter mentioned "initial inflammatory features," this was in reference to symptoms of polyarthralgia, muscle weakness, fatigue, and stiffness rather than her otherwise reported edema. (Ex. 41, p. 2.) Dr. Mangru never assessed petitioner for her alleged post-vaccination edema or chest pain and never endorsed edema or chest pain as part of her MCTD presentation. Moreover, when petitioner initially went to her primary care provider post-vaccination and reported edema, the physician was unsure whether any edema was actually present based on physical exam and, in any event, did not assess it as a post-vaccination reaction. (Ex. 5, p. 54.) And, although petitioner subsequently reported chest pain that she paralleled to her prior

alleged vaccine reaction, no underlying cause for her chest pain was found. (Ex. 5, p. 47; Ex. 25, pp. 10-12.) To the extent petitioner's primary care provider assessed a hypersensitivity reaction in response to her complaint of chest pain (Ex. 5, p. 49), Dr. Mangru never adopted any similar finding and respondent's expert, Dr. Maverakis, refuted the notion that MCTD constitutes a hypersensitivity reaction. (Ex. C, p. 14.) Moreover, even if petitioner's initial 2017 symptoms did reasonably parallel her prior 2011 condition, petitioner's prior medical records from 2011 are explicit in suspecting that petitioner's prior pericardial effusion (and secondary joint pain) was the result of a viral illness (Ex. 20, p. 460) and her treaters specifically noted that they doubted her vaccination(s) were the cause of her overall symptom presentation (*Id*. at 271).

Thus, for all the reasons discussed above, there is not preponderant evidence of a logical sequence of cause-and-effect implicating petitioner's September 29, 2017 flu vaccination as a cause of her condition and petitioner therefore has not met her burden of proof under *Althen* prong two.

c. *Althen* prong three

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1278. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.*; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *mot. for recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd*, 503 F. App'x 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877, at *26 (Fed. Cl. Spec. Mstr. May 30, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

Because petitioner has not presented a reliable theory of causation under *Althen* prong one, she likewise cannot satisfy *Althen* prong three. In any event, even if petitioner did satisfy *Althen* prong three based on broader concepts of autoimmunity, satisfaction of *Althen* prong three alone would not permit her to prevail. *Veryzer v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 344, 356 (2011) (explaining that a "temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury."); *Hibbard v. Sec'y of Health & Human Servs.*, 698 F.3d 1355, 1364-65 (Fed. Cir. 2012) (holding the special master did not err in resolving the case pursuant to Prong Two when respondent conceded that petitioner met Prong Three). However, if this case were to turn on *Althen* prong three, then it would be necessary to resolve the disputed diagnosis in this case, given that this could have a bearing on whether petitioner's pre- and post-vaccination medical history, which is complex and inclusive of musculoskeletal complaints occurring over years, should be viewed as one unified condition predating her vaccination.

VII. Conclusion

There is no question that petitioner has suffered and that the events discussed throughout this decision have affected her life. She has my sympathy and I do not question her sincerity in bringing this claim. However, for all the reasons discussed above, I find that petitioner has not met her burden of proof in this case. Therefore, this case is dismissed.[22]

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master

[22] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.